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July 27, 1999

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Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Re: 99P-1340/CP 1 Petition to the FDA to have Calvin Klein's Eternity eau de parfum declared "misbranded"

Dear Sir or Madam:

In May, 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded. I support this petition. Your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10 specifically state:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

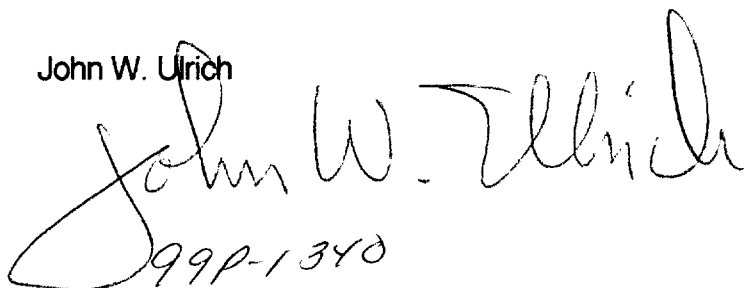
"Warning--The safety of this product has not been determined."

"Eternity" contains ingredients whose safety has not been substantiated yet it does not contain the required warning label on its packaging.

I have no doubt that some day in the future the ingredients of "Eternity" and other common scented products will be banned as a public health menace. My wife can't wear perfumes and has unusually strong reactions to the perfumes worn by others. Exposures to "Eternity" and similar products render her dizzy and mentally confused. Walking is difficult. Her ability to read is impaired. I can't imagine what long term effects are taking place in some of the people who actually apply these substances to their skin.

Of course my wife's experiences are only anecdotal evidence that "Eternity" and perfumes like it may contain harmful substances. But I have personally encountered numerous other individuals who report unpleasant symptoms when exposed to such perfumes. Such evidence should at least raise the alarm that study is needed before we tell the American consumer that "Eternity" is a safe product to use. The American consumer is counting on product labels to warn them when they are using untested products. Presumably this is the reason for your regulations concerning the labeling of cosmetics. I respectfully suggest that you enforce your regulations.

John W. Ulrich


99P-1340

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